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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,272	02/06/2002	H. Andrew Strong	273012012500	1974

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/072,272	STRONG ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 5-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2006 has been entered.

Claim(s) 3-4 have been cancelled. Claim(s) 20 has been added. Claim(s) 1-2, 5-20 are pending. Claim(s) 1, 5 have been amended. Claim(s) 1-2, 5-20 are examined herein.

Applicant's amendments have rendered the 112 rejection of the last Office Action moot, therefore hereby withdrawn. Applicant's arguments regarding the 103(a) rejection of the last Office Action have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 5-12, 14-18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over TAP Report 1 ("Photodynamic Therapy of Subfoveal Choroidal Neovascularization in Age-related Macular Degeneration with Verteporfin." Arch Ophtalmol. 1999; 117:1329-1345) (the TAP Report).

The instant claims are directed to methods of treating an occult choroidal neovascular (CNV) lesion comprising administering photodynamic therapy to a subject having Occult CNV, wherein the subject is assessed as having either or both (a) a small lesion with a size less than about 4-5 disc areas or (b) poor visual acuity of less than about 65 letters prior to treatment and wherein the occult lesion comprise an occult component of at least about 50% to 100% of the lesion.

The TAP Report teaches the instantly claimed method. Tap Report teaches methods of administering verteporfin, a green porphyrin (which is also known as BPD-MA, see Reg Number 129497-78-5) to patients suffering from Occult CNV. (see page 1330 under the heading Patient Selection, last para.). Out of the 402 Patients in the Vertoporfin arm of the study, at least 305 patients had evidence of Occult CNV (see Table 2 at page 1334, last criteria under the category Evidence of Occult CNV). Further,

out of the same 402 patients at least 199 patients had a visual acuity of less than 53 letters (see Table 2, Vertoporfin Arm, under the category Visual Acuity criteria). Thus, at least about 100 patients who had received a photodynamic regimen of Verteporfin, had evidence of Occult CNV with visual acuity of less than 65.

Examiner also states that among the population in the Verteporfin Arm, 259 appear to have lesion size of less than 6 disc areas (see page 1335, table 2, under Vertoporfin Arm, Under the Area of Lesion, MPS Disc Areas criteria). Therefore, the population who showed Occult CNV in the TAP Report and further received verteporfin, are the same as the instantly claimed population. Said population received Verteprofin solution in amount of about 6 mg/m 2 (see abstract, also page 1332, at 1st col). Fifteen minutes after administration of the Verteprofin the CNV lesions were irradiated with a laser light for about 83 seconds in a light exposure of 50 J/CM2. (see col 1 page 1332). Accordingly, the limitations of claims 14-18 are met.

All method steps of the instantly claimed process are described for the population who showed Occult CNV prior to the therapy in the TAP Report Verteporfin Arm. Accordingly, the instantly claimed intended purpose is inherently achieved in the said population.

Applicant is also informed that the recitation of 45% efficacy of therapy in Occult CNV group, as recited in page 1338 is not a teaching away, because such conclusion does not mean that no patient has benefited from the methodology described in Vertopoifin Arm of the TAP Report. Rather, such percentage is only viewed as a comparison to the control group. Examiner adds that the 33.1% of the TAP Report's

Verteporfin Arm included lesion. TAP Report only fails to explicitly state that the patients in the Verteporfin Arm of the study had an occult component of at least about 50% to 100% of the lesion.

Nevertheless, absent a showing of unexpected results or evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the method steps of TAP Report to treat patients with occult CNV lesion having an occult component of at least about 50% to 100% of the lesion, because as shown by the Report, one of ordinary skill in the art would have had a reasonable expectation of success to observe some degree of improvement in ocular condition of the patients suffering from said occult CNV.

Claims 1-2, 5-20 rejected under 35 U.S.C. 103(a) as being unpatentable over TAP Report in view of Zeimer US Patent 5,935,942.

The teachings of TAP report are described above. TAP report only fails to specifically describe attachment the use of a targeting ligand and the dosing of its photosensitizer per body weight of subjects.

Zeimer is used to describe the same process as in TAP report except that the photosensitizer is encapsulated or coupled with a targeting or tissue specific agent (see col 12, lines 28-50; col 14, lines 15-col 24). The process of Zeimer employs targeted liposomes (col 25-26) for patients having Occult CNV.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add a targeting agent, such as an antibody, to the photosensitizer

employed in TAP report, because as suggested by Zeimer, the ordinary skill in the art would have had a reasonable expectation of success in improving the clinical outcome.

Further, absent a showing of criticality, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the dosing ranges of the photosensitizer in TAP report by routine experimentation and express it based on the body weight of subjects.

Response to Arguments

Applicant argues that the results found in Table 2 of the present specification shows a significant and advantageous difference in the verteporfin-treated group in comparison to the placebo-treated group for a subset of subjects having an occult lesion, in contrast to what was found in the TAP Report 1. Applicant points to Table 5 (pg. 1340) in the Tap Report 1, where there was no significant differential between verteporfin-treated patients and placebo-treatment group. Therefore, in this manner, there is allegedly no motivation to select a particular subgroup.

This is not persuasive because Applicant's arguments are not commensurate with the scope of the claims, particularly on the subset of the patient population. Table 5 (pg. 1340) of the Tap Report 1 tests for a group of patients having an occult lesion between 0 to 50%, whereas the claim 1 of the instant application defines the patient population as having an occult component of 50 to 100% of the lesion. Therefore, the subset of patients is not the same.

In fact, a large statistical difference is observed in Table 5 (pg. 1340) of the Tap Report on patients having an occult lesion of greater than 50%. Further support for this

result is given on page 1338 where it states "subgroup analysis showed a large treatment benefit when the lesion was predominately classic CNV (i.e., the area of classic CNV occupied ≥50% of the area of the entire lesion) at baseline, with 33% of the 159 eyes treated with verteporfin compared with 50% (61%) of the 84 eyes given placebo losing 15 or more letters at the 12 month examination."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER